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Medical Coverage Policy

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Speech Generating Devices

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses speech generating devices. Speech generating devices assist individuals with severe speech impairments with the ability to meet functional speaking needs.

Coverage Policy

Coverage for speech generating devices varies across plans. Refer to the customer's benefit plan document for coverage details.

Many benefit plans exclude coverage for "aids or devices that assist with nonverbal communications." However, unless specifically excluded, speech generating devices that use synthesized speech are covered if criteria are met.

When covered, coverage for speech generating devices is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments.

If coverage for the specific speech generating device is available, the following conditions of coverage apply.

Covered Speech Generating Devices:

A speech generating device is generally limited to a device that uses synthesized speech. The following speech generating devices are considered medically necessary when the criteria outlined below are met:

HCPCS Codes	Description
E2508	Speech generating device, synthesized speech, requiring message formulation by spelling and access by physical contact with the device
E2510	Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access

A speech generating device that utilizes synthesized speech (HCPCS codes E2508, E2510) is considered medically necessary DME when ALL of the following criteria are met:

- The individual has a permanent and severe expressive speech impairment such as dysarthria, anarthria, aphasia, or aphonia, including a severe speech impairment associated with an autism spectrum disorder or pervasive developmental disorders.
- A speech evaluation, conducted by a speech-language pathologist, has documented the severity of the individual's disability, specific to their primary language.
- Speaking needs cannot be met using natural communication methods.

- Other forms of treatment have failed, are contraindicated, or are otherwise not appropriate.
- A speech generating device is available in the individual's primary language and is being requested for the sole purpose of speech generation.
- The speech generating device is used primarily for speech, but may also include the following:
  - the capability to generate email, text, or phone messages which allows the individual to communicate remotely
  - the capability to download updates to the covered features of the device from the manufacturer or supplier of the device

The following are considered not medical in nature, and thus are considered not medically necessary:

- tablet devices (e.g., iPads) that are not dedicated to the sole purpose of communication
- multi-purpose, general consumer electronic devices such as computers, smart phones, personal digital assistants (PDAs), electronic mail devices and pagers, because they are not medical in nature.

Health Equity Considerations

Approximately 10% of the U.S. adult population has a speech, language, and/or voice disability, collectively referred to as communication disabilities. An increasing number of studies demonstrate that persons with communication disabilities have worse health and health care outcomes as compared to those without communication disabilities (Morris, 2022). People with communication disabilities have significantly higher rates of multiple chronic conditions. These results differ by type of communication disability, with 40.4% of those with voice only and 62.7% of those with speech, language, and voice disability having two or more chronic conditions. In comparison, 24.5% of those without a communication disability have multiple chronic conditions, controlling for other demographic characteristics, such as race, ethnicity, age, and gender (Stransky et al., 2018). In addition, individuals with communication disabilities are more likely to experience a preventable adverse medical event in the hospital compared to those without communication disabilities (Bartlett et al., 2008).

General Background

Speech Generating Devices

Speech generating devices (SGDs) assist individuals with severe speech impairments with the ability to meet their functional speaking needs. An SGD may also be considered an electronic augmentative and alternative communication (AAC) device that generates speech output. AAC involves the attempt to compensate for the impairments of individual with severe expressive speech impairment.

Speech is the articulation and phonation of language sounds. Language refers to symbolic communication and is the ability to converse, comprehend, repeat, read, and write. Communication disorders may include (Bradley, et al., 2016; National Institute on Deafness and Other Communication Disorders [NIDCD]):

- Dysarthria: This disorder involves the abnormal articulation of sounds or phonemes. This group of speech disorders is caused by disturbances in the strength or coordination of the muscles of the speech mechanism as a result of damage to the brain or nerves.
- Apraxia: The disorder stems from a deficit in the planning and programming of the sequence of movements for speech and occurs despite the fact that the same muscles move normally when speech is not involved The most common cause is stroke; however, apraxia may also occur with tumor or traumatic brain injury.
- Aphasia: This is the impairment of an individual's ability to understand and formulate language. Aphasia results from brain damage, typically involving the language-dominant (i.e., left) cerebral hemisphere. This disorder is a total or partial loss of the ability to use or understand language; usually caused by stroke, brain disease, or injury.
- Anarthria: This disorder is a total loss of ability to articulate.

SGDs have been divided into these technologically and clinically distinct categories:

- SGD with digitized speech output
- SGD with synthesized speech output, includes these two types:
  - devices which requires message formulation by spelling and device access by physical contact, with direct-selection techniques
  - devices which permits multiple methods of message formulation and multiple methods of device access

The devices vary in the features found in each. The features may include:

- methods of displaying language/message components: this may include dynamic or static display
- methods of storing and retrieving language: this includes the levels and encoding strategies utilized (e.g., numeric, letter, semantic)
- rate enhancing method (e.g., message prediction)

Digitized speech devices utilize words or phrases that have been recorded by an individual other than the SGD user for playback upon command of the SGD user. They are also referred to as devices with whole message speech output.

Unlike the prerecorded messages of digitized speech, synthesized speech technology translates a user's input into device-generated speech. Users of synthesized speech devices are not limited to prerecorded messages but rather can independently create messages as their communication needs dictate. These devices require that the user make physical contact with a keyboard, touch screen or other display containing an alphanumeric display.

Synthesized speech devices permit the user multiple methods of message formulation and multiple methods of access. Multiple methods of message formulation must include the capability for message selection by two or more of the following methods: letters, words, pictures or symbols. Multiple methods of access must include the capability to access the device by two or more of the following methods: direct physical contact via a keyboard or touch screen, or indirect selection techniques via a specialized access device such as a joystick, a head-mouse, an optical head-pointer, a switch, a light pointer, an infrared pointer, a scanning device, or Morse code.

Personal digital assistants (PDAs) are handheld devices that integrate the functions of a small computer with features such as a cell phone, personal organizer, electronic mail or pager. Information may be entered either via a pen-based system using a stylus and handwriting recognition software, via a keyboard, or it may be downloaded from a personal computer using

special cables and software. These devices, including, but not limited to, PDAs, computers, smart phones, electronic mail devices and pagers are not used for the sole purpose of speech generation, are not considered to be speech generating devices and not medical in nature. A dedicated tablet (e.g., iPad) may be used as a speech generating device (SGD) – this is when the device is only capable of speech generating abilities and functions as a SGD.

Speech Evaluation
A speech evaluation is performed in order to determine the severity and motor deficit of each individual. This evaluation is conducted by a speech-language pathologist (SLP). The SLP is a licensed health professional, educated at the graduate level in the study of human communication, its development and its disorders. The SLP must hold a Certificate of Clinical Competence (CCC) in speech-language pathology from the American Speech-Language-Hearing Association. The SLP will be able to determine, based on the evaluation and on the natural course of the disease or condition, when a speech generating device or treatment is necessary and what type of device or treatment would best meet the needs of the specific patient in question.

Prior to the delivery of the SGD, the patient has had a formal evaluation of their cognitive and communication abilities by a SLP. The formal, written evaluation should include, at a minimum, the following elements:

- current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment
- an assessment of whether the individual's daily communication needs could be met using other natural modes of communication
- a description of the functional communication goals expected to be achieved and treatment options;
- rationale for selection of a specific device
- demonstration that the patient possesses a treatment plan that includes a training schedule for the selected device
- the cognitive and physical abilities to effectively use the selected device
- for a subsequent upgrade to a previously issued SGD, information regarding the functional benefit to the patient of the upgrade compared to the initially provided SGD

Individuals with severe disabilities present a wide range of physical, cognitive, linguistic, sensory and motor deficits, as well as different daily communication needs. Upon completion of the evaluation, a speech generating device may be recommended according to the permanence and severity of expressive speech impairment, as well as the short- and long-term goals for these individuals.

Once the speech assessment of the individual has been completed, the following clinical indicators are used to evaluate the appropriate category of speech generating devices required to meet the individual’s communication needs:

- The individual has a communication disability with a diagnosis of severe dysarthria, apraxia and/or aphasia.
- The individual’s communication needs that arise in the course of current and projected daily activities cannot be met using natural communication methods.
- The individual requires a speech output communication device to meet his/her functional communication goals.
- The individual possesses the linguistic capability to formulate language (i.e., messages) independently.
- The individual will produce messages most effectively and efficiently using spelling.

- The individual will require a speech generating device with extensive language storage capacity and rate enhancement features.
- The individual will access the device most effectively and efficiently by means of physical contact, direct-selection technique, such as a finger, other body part, stylus, and hand-held pointer, head-stick or mouth-stick.

The use of only one speech generating device or speech generating program at a time is considered a medical necessity. This device or program should be limited to the primary language of the individual, not multilingual in capability.

Upgrades to these devices or programs must first be assessed through a speech-language evaluation. The SLP evaluation should clearly document the medical need for the upgrade.

Synthesized speech devices that require message formulation by spelling and access to physical contact with the device include, but are not limited to the following devices (i.e., HCPCS codes E2508, E2510):

- Allora (ZYGO Industries, Inc., Fremont, CA)
- E-talk Tablet (Synapse Adaptive, San Rafael, CA)
- Optimist MMX (ZYGO Industries, Inc., Fremont, CA)
- Nova Chat 8, Nova Chat 10 (Saltillo Corp., Millersburg, OH)
- Tobii Dynavox T7, Tobii Dynavox T10, Tobii Dynavox T15, Tobii I-12, Tobii I-15 (TobiiATI, Dedham, MA)
- Accent™ 800-M (Prentke Romich Company, Wooster, OH)
- Accent™ 1000-M (Prentke Romich Company, Wooster, OH)
- QuickTalker™ Freestyle (AbleNet, Inc., Roseville, MN)
- QuickTalker™ Freestyle mini (AbleNet, Inc., Roseville, MN)

U.S. Food and Drug Administration (FDA)
SGDs are classified as Class II devices by the U.S. Food and Drug Administration (FDA) and are exempt from the premarket notification procedures. The FDA has described these devices as: "system, communication, powered" devices." The FDA identifies them as, "A powered communication system is an AC- or battery-powered device intended for medical purposes that is used to transmit or receive information. It is used by persons unable to use normal communication methods because of physical impairment."

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	National Coverage Determination (NCD) for Speech Generating Devices (50.1)	07/29/2015
LCD	CGS Administrators Noridian Healthcare Solutions	Local Coverage Determination (LCD): Speech Generating Devices (SGD) (L33739)	01/01/2020

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Effective date 01/15/2025

Notes:

1. This list of codes may not be all-inclusive since the AMA and CMS code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Synthesized Speech Generating Devices

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
E2508	Speech generating device, synthesized speech, requiring message formulation by spelling and access by physical contact with the device
E2510	Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access

Not Medically Necessary

Considered not medically necessary when used to report multi-purpose, general consumer electronic devices:

HCPCS Codes	Description
E1399	Durable medical equipment, miscellaneous

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Removed policy statements on speech generating device accessories. • Removed policy statements on speech generating devices, digitized speech, using pre-recorded messages.	04/15/2024
Focused Review	• Added policy statement for multi-purpose, general consumer electronic devices.	01/15/2025